K050172

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Attachment 7

510(k) Summary

Cardiomedics, Inc.
CardiAssist Counter Pulsation System – Series 4000

1.	Date Prepared:	January 20, 2005
2.	Submitter's Name: and Address	Cardiomedics, Inc. 18872 Bardeen Avenue Irvine, CA 92612
3.	Contact Person:	John Hutchins, Vice President, Marketing and Clinical Affairs Cardiomedics, Inc. Ph: (949) 863-2500 x104 Fax: (949) 474-2446 Email: hutch@Cardiomedics.com
4.	Device Name:	CardiAssist Counter Pulsation System
	Proprietary Name:	CardiAssist Counter Pulsation System - Series 4000
	Classification Name:	Device, Counter-pulsating, External
5.	Predicate Device:	The CardiAssist Series 4000 Counter Pulsation System is equivalent in function and intended use to the currently marketed CardiAssist ECP System, Mark 3000 cleared for market entry under 510(k) K023427 on January 7, 2003 as well as technologically and functionally equivalent to the Nicore NCP-1 Device, cleared for market entry under 510(k) K023016 on December 4, 2002.

6. Device Description:

The Cardiomedics CardiAssist External Counter Pulsation System - Series 4000 is a non-invasive circulatory assist device, which provides increased circulation via external counterpulsation (ECP) for the treatment of ischemic heart disease including congestive heart failure, chronic angina pectoris, acute myocardial infarction and cardiogenic shock. External counterpulsation therapy improves cardiac function by enhancing the perfusion of the coronary vasculature, the development of coronary collateral circulation, and by reducing the workload of the heart.

The CardiAssist External Counter Pulsation System - Series 4000 consists of the portable console containing the computer and pumps with a touch screen for user interface, an integral patient chart printer, and leg cuffs and hoses. Additional components provided with the System include a finger plethysmograph and 5-lead ECG cable and leads (12 lead optional) and blood pressure cuff.

This CardiAssist ECP System sequentially compresses the legs from the calves, thighs and buttocks, 40 milliseconds apart, by inflating three sets of flexible fabric cuffs during diastole. This results in movement of blood from the legs to the heart and entire upper body. Pressure, up to 310 mmHg, is applied with the timing and duration of each pulse, synchronized with the patient's ECG. When properly triggered, the pressure pulses applied to the vascular bed of the legs and buttocks transmit retrograde pressure through the entire vascular system. At the aorta, the aortic valve prevents retrograde flow into the left ventricle. Thus, a peak pulse of diastolic pressure occurs at or above systolic levels, which increases the driving pressure in the coronary vasculature.

7. Intended Use:

The Cardiomedics, Inc., CardiAssist External Counter Pulsation System - Series 4000, is intended to provide external counterpulsation (ECP) for the treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction and cardiogenic shock. Use of this device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.

8. Comparison of Technological Characteristics

Technological characteristics of this device which are similar to those of the Cardiomedics 3000 Series predicate system include: the triggering mechanism (patient's ECG R-wave); microprocessor based control system; emergency system power down; limited maximum pressure used for treatment; through-hole circuit board; safety interlock requiring external ECG signal before treatment can start; and the Cardiomedics cuff system which eliminates the need for vacuum cuff deflation.

Technological characteristics of this device which are similar to those

of the Nicore predicate device include: the triggering mechanism (patient's ECG R-wave), microprocessor based control system, limited maximum pressure used for treatment, operator's console and data display with mouse based interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Cardiomedics, Inc..
c/o Mr. John Hutchins
18872 Bardeen Avenue
Irvine, CA 92612

Re: K050172
Cardiomedics CardiAssist Counter Pulsation System – Series 4000
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter Pulsation Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: January 20, 2005
Received: February 1, 2005

Dear Mr. Hutchins:

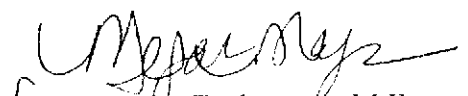
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 8 – Statement of Intended Use

510(k) Number: K050172

Device Name: CardiAssist Counter Pulsation System - Series 4000

Indications for Use:

The Cardiomedics, Inc., CardiAssist Counter Pulsation System - Series 4000 is intended to provide external counterpulsation (ECP) for the treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction and cardiogenic shock. Use of this device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.

Prescription Use ☒ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050172